# Mammography Continuing Education (MEU) Policy For Mammography Quality Standards Act (MQSA) Certified Inspectors November 1, 1999

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# Mammography Continuing Education (MEU) Policy For Mammography Quality Standards Act (MQSA) Certified Inspectors

## BACKGROUND AND GOAL

42 USC 262 Subpart 3D(d)(1)(B)(i) of the Mammography Quality Standards Act (MQSA) requires the establishment of minimum qualifications and appropriate training for inspectors. Following initial training in basic radiation physics, quality assurance, quality control, mammography and inspection procedures, it is important that certified MQSA inspectors maintain and improve their understanding of inspection procedures and the physical principles underlying these procedures. Further, continuing education in recent developments in mammography, as well as state-of-the-art mammography equipment contributes to the knowledge and expertise of the MQSA Inspector. NOTE: Reference the "Continuing Experience Policy for MQSA Inspectors" and "Audit Policy" for additional MQSA Inspector requirements.

- POLICY

### Continuing Education Requirements To Maintain Active Status

Following the third anniversary date of certification and annually thereafter, an MQSA-certified Inspector shall have taught or earned a total of 15 Mammography Continuing Education Units (MEUs) (15 contact hours) during the 36 months immediately preceding the date of the inspector's annual MQSA audit or the last day of the calendar quarter preceding the audit or any date in between the two. The inspector may choose their dates each assessment year in determining the 36-month period that the MQSA FDA Auditor shall use to confirm that the continuing education requirements were met (Reference page 2 - Acceptable MEUs for guidance concerning specific teaching requirements and acceptable MEUs.)

The required 15 MEUs are a minimum for certified inspectors. However, FDA encourages inspectors to obtain more than the minimum requirement up to the allotted funding (Reference Funding – pg. 4). MQSA FDA Auditors, on the other hand, are required to maintain a total of 20 MEUs over 36-months (five additional) which are earned through attendance at FDA sponsored Auditor's Workshops.

In addition to the required MEUs, the Division of Mammography Quality and Radiation Programs (DMQRP), Food and Drug Administration (FDA), may require participation in additional mandatory workshops, training courses, homestudy or teleconferences such as those concerned with major changes in MQSA regulations or changes in the inspection

software. DMQRP will assess training needs and notify inspectors of any mandatory training.

Acceptable MEUs

Training, conferences, and/or homestudy for which MEUs can be earned parallel the FDA issued guidance concerning acceptable areas for meeting the continuing education requirements for mammography facility personnel as required by the MQSA.

Both the guidance and the MQSA regulations state that all continuing education credits related to the diagnosis or treatment of breast disease or to other areas that aid facility personnel in improving the quality of mammography are recognized in meeting the MQSA personnel requirements. Sources include:

1. Training, conferences or homestudy recognized by an organization that decides the number of units that may be awarded and must document in writing the number awarded;

2. Teaching and/or preparation time for a specific course, training session or conference. The inspector can count the course only once in a 36-month period for credit(s), regardless of the number of times taught, during the period. Teaching and preparation time must be reviewed and approved by an organization that grants continuing medical education units to an individual. The organization decides the number of units that may be awarded and must document in writing the number awarded;

3. Credit for continuing medical education by publishing a paper if they are awarded credits or units by an organization that grants continuing medical education units to an individual for such publications. The organization decides the number of units that may be awarded and must document in writing the number awarded.

PRE-APPROVAL PROCESS

The FDA has eliminated the required MEU **course appropriateness** pre-approval process. Inspectors shall work through their respective FDA or State Supervisors to coordinate approval of continuing education. This method eliminates a burdensome administrative process. It places the responsibility for selecting and tracking acceptable continuing education on the MQSA inspector, who currently assess facility personnel in meeting their continuing education requirements, as defined by the MQSA. **However, a funding availability verification process is required as outlined below.**

- STATE INSPECTORS

The FDA requires funding availability **verification** by the Conference of Radiation Control Program (CRCPD) Directors via the MEU Funding Verification Form (Enclosure 1)+. Inspectors shall submit the completed form to the CRCPD, including inspector supervisor approval per the instructions on the form, along with course

documentation to support proposed travel dates (e.g., agenda). The CRCPD will fax a signed form back to the inspector for training initiation or denial.

+Note: This requirement does not apply to States as Certifiers (currently Illinois and Iowa).

- FDA INSPECTORS

The FDA requires funding availability **verification** by Steve Toigo, Division of Federal and State Relations, Office of Regulatory Affairs via the FDA Inspector - MEU Funding Funding Verification Form (Enclosure 2). Inspectors shall submit the completed form, including inspector supervisor approval per the instructions on the form, along with course documentation to support proposed travel dates (e.g., agenda). Mr. Toigo will fax a signed form back to the inspector for training initiation or denial.

FUNDING LEVELS

- STATE INSPECTORS

Effective June 1998, new inspectors or current* inspectors whose certification was renewed are allotted MQSA funds totaling $1,300 each for 36 months by FDA through each state's MQSA contract.

Verified funding must be used for MEU expenditures for the specifically identified inspector. Expenditures may include costs associated with registration, tuition fees, course materials, and appropriate travel expenses. Salary costs will **not** be charged against the $1,300 allowable funds.

State inspectors shall submit final expenditures (e.g., copy of state travel voucher) to the CRCPD within one month of the training. Additional training opportunities may be denied by CRCPD without documentation of previous actual training expenditures.

*Note: Existing State inspectors who are currently receiving $1,800 will be affected by the MEU funding modification in what would have been their next three-year certification period. However, if an inspector currently allotted $1,800 moves to another state or returns to the MQSA Program after being inactive, his/her MEU allotment will be $1,300 every 36 months from the date of initial training.

- FDA INSPECTORS

Effective June 1998, new inspectors or current* inspectors whose certification was renewed will be allotted MQSA funds totaling $1,300 each through the Office of Regulatory Affairs (ORA), FDA. Funding distributed must be used for MEU expenditures for the specifically identified inspector. Expenditures may include costs associated with registration, tuition fees, course materials, and appropriate travel expenses. Salary costs will **not** be charged against the $1,300 allowable funds. Reimbursement to FDA

inspectors for MEU costs comes through the FDA Office of Regulatory Affairs (Contact Steve Toigo, ORA at 301-827-2906).

FDA inspectors shall submit final expenditures (e.g., copy of travel voucher) to Steve Toigo, ORA within one month of the training. Mr. Toigo may deny additional training opportunities without documentation of previous actual training expenditures.

*Note: Existing FDA inspectors who are currently receiving $1,800 will be affected by the MEU funding modification in what would have been their next three-year certification period. However, if an inspector currently allotted $1,800 moves to another state or returns to the MQSA Program after being inactive, his/her MEU allotment will be $1,300 every 36 months from the date of initial training.

## ACCEPTABLE DOCUMENTATION OF CONTINUING EDUCATION

Each inspector must maintain evidence of MEUs earned and submit this documentation to the FDA MQSA Auditor for review at their annual audit (conducted each federal fiscal year between October 1 - September 30)*. Documentation of satisfactory completion of training includes course certificates or a sponsor's listing (e.g., RSNA, ASRT) of completed continuing education (lecture or course agendas, as necessary). Auditors shall submit the number of MEUs earned by the inspector in their audit reports.

*To avoid additional facility disruption auditors will physically perform the inspector records assessment just prior to or following the audit.

## STEPS FOR REESTABLISHING CONTINUING EDUCATION QUALIFICATIONS

An inspector who fails to maintain the required continuing education shall reestablish his/her qualifications before resuming independent inspections, as follows:

- The inspector shall obtain a sufficient number of additional credits in mammography to bring his/her total up to the required credits in the previous 36 months before resuming independent inspections. Additionally, the inspector shall provide documentation of MEUs earned to requalify to the inspector's FDA Auditor at the time of their audit. After requalifying, inspectors are still responsible for maintaining their required MEUs in the 36-month period.

  NOTE: The date on which the inspector was initially certified as an MQSA inspector does not change due to taking time off or not meeting the continuing education requirements.